IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ABBVIE INC., ABBVIE DEUTSCHLAND GMBH & CO. KG Plaintiff, v. MYLAN LABORATORIES LTD., MYLAN LABORATORIES INC., and MYLAN PHARMACEUTICALS INC., Defendants.	C.A. No. 1:09-cv-01586 Judge Jorge Luis Alonso [redacted]

DEFENDANTS' RESPONSIVE CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals"), Mylan Laboratories Inc., and Mylan Laboratories Ltd. (collectively, "Mylan") submit this responsive brief in support of their proposed claim constructions for the disputed claims terms of asserted U.S. Patent Nos. 7,148,359 ("the '359 patent"), 7,364,752 ("the '752 patent"), 8,025,899 ("the '899 patent"), 8,268,349 ("the '349 patent"), 8,309,613 ("the '613 patent"), 8,377,952 ("the '952 patent"), 8,399,015 ("the '015 patent"), 8,470,347 ("the '347 patent"), and 8,691,878 ("the '878 patent"), (collectively, the "patents-in-suit").

Mylan's proposed claim constructions best align with the intent of the patentees of each of the patents-in-suit and are fully supported by intrinsic evidence. The constructions proposed by Plaintiffs AbbVie Inc. and AbbVie Deutschland GmbH & Co. KG (collectively, "AbbVie"), however, seek to improperly broaden the disclosed inventions in a failed effort to read on Mylan's accused products. Accordingly, Mylan respectfully submits that the Court should adopt Mylan's proposed constructions for each of the disputed terms.

II. STATEMENT OF FACTS

A. Asserted Patents and Procedural Background

Mylan Pharmaceuticals filed ANDA No. 91-202 seeking the United States Food & Drug Administration's approval for generic lopinavir/ritonavir tablets 200/50 mg and 100/25 mg. AbbVie holds the New Drug Application ("NDA") for products containing the relevant active ingredients, ritonavir and lopinavir, marketed under the brand name Kaletra® tablets.

Each of the patents-in-suit is listed in the Orange Book for Kaletra® tablets, and Mylan filed a Paragraph IV certification for each of them in its ANDA.[1] AbbVie has asserted the following claims from each of the patents in suit:

[1] *See* Ex. A; *see also* 21 U.S.C. § 355(b)(2)(A)(iv).

- ’359 patent: Claims 1 and 4-7
- ’752 patent: Claims 8, 11, 13, 16-20, 22, and 25-28
- ’015 patent: Claims 1-8, 10-12, 15, 17-22, 24-29, and 31
- ’899 patent: 1, 2, 4-8, 10, and 12
- ’349 patent: 1-5 and 7
- ’613 patent:1-15 and 17-18
- ’952 patent: 1-28
- ’878 patent: 1-8 and 10-20
- ’347 patent: 1-3, 5, 6, 8-10, 20, 21, and 23

B. Overview of the Patents-in-Suit

In general, each of the patents-in-suit relates to protease inhibitor pharmaceutical formulations used in the treatment of HIV. First, the ’359 patent is purportedly directed to “[a] new crystalline polymorph of ritonavir and methods for its use and preparation.” (Ex. B at Abstract). The ’359 patent claims “substantially pure amorphous ritonavir” and compositions of the same and discloses the methods of making the “substantially pure amorphous ritonavir” using crystal Form I ritonavir for pharmaceutical compositions. (*See, e.g.*, *id.* at col. 1, ll. 15-25, Claims 1, 4; *see also id.* at col. 3, ll. 36-46 (“Substantially pure amorphous ritonavir is prepared from the Form I crystalline polymorph of ritonavir by melting Form I ritonavir and rapidly cooling the melt ... [or] by slowly adding a solution of ritonavir Form I in a suitable solvent … to an anti-solvent ….”)).

Next is the ’752 patent, which differs from the ’359 patent in that it purports to disclose solid dispersions of amorphous ritonavir and the select requisite excipients that allegedly help form such dispersions. The ’752 patent is purportedly directed to “[a] pharmaceutical

composition … compris[ing] a solid dispersion of an HIV protease inhibitor [such as ritonavir] in a water soluble carrier, such as PEG, having enhanced bioavailability and improved dissolution properties." (*See, e.g.*, Ex. C. at Abstract). The '752 patent purports to state that the alleged invention improves the bioavailability of ritonavir via an allegedly novel solid dispersion method in which "[t]he solid matrix has the compound finely dispersed (molecular dispersion) in such a way that dissolution of the drug is maximized," as is absorption in the body. (*Id.* at col. 3, ll. 32-36). As described in the '752 patent, this method requires dissolving ritonavir in a solvent and then dispersing that mixture into a water soluble carrier, followed by evaporation of the solvent, which results in amorphous ritonavir being dispersed in a matrix. (*Id.* at col. 3, ll. 1-36). According to the '752 patent, the method's resulting mass is then purportedly ground into smaller particles that are used to make conventional delivery systems, *i.e.* by filling into capsules or compression into tablets. (*Id.* at col. 3, ll. 41-43).

Several years after the filing of the '752 patent, the specification that ultimately resulted in the issued '899, '015, '349, '613, and '878 patents was filed. Each of these later patents allegedly relate to improving the solubility and bioavailability of protease inhibitor pharmaceutical compositions via solid dispersion formulations, and allegedly disclose the use of different excipients in the formulation and different dispersion manufacturing processes in addition to the solvent evaporation method of the '752 patent. (*See*, *e.g.*, Ex. D at Abstract). For example, the shared specification of these patents purports to disclose that the alleged improvements are achieved by creating a dosage form that includes ritonavir and/or lopinavir in a solid dispersion, solid solution, or glassy solution with a water-soluble polymer *and* a surfactant. (*Id.* at Abstract). Additionally, the specification makes clear that "[v]arious

techniques exist for preparing [the disclosed] solid solutions including melt-extrusion, spray-drying and solution-evaporation with melt-extrusion being preferred." (*Id.* at col. 6, ll. 13-15).

The '952 patent similarly relates to solid dispersions of protease inhibitors, but purports to disclose formulations that allegedly "provide a more consistent blood level of the [protease inhibitors] among patients taking such therapy which helps insure [sic] an effective therapeutic benefit and less adverse events ... without regard to whether or not the patient has eaten or what type of meal was eaten." (Ex. E at col. 2, ll. 25-31.)

Lastly, the '347 patent, which shares three of the same inventors as the '899, '015, '349, '613, '952 and '878 patents, purports to disclose solid "self-emulsifying formulations based on an active ingredient component and a formulation base" that includes a lipid component and a binder component which are preferably manufactured using melt-extrusion. (*See* Ex. F at Abstract). The specification of the '347 patent purports to disclose that the claimed self-emulsifying formulations, which "spontaneously form emulsions in water or aqueous media," increase the bioavailability of active ingredients with low solubility, such as ritonavir. (*See id.*; *see also id.* at col. 1, ll. 15-20 ("It is often desired to be able to employ active ingredients in emulsified form … [in which] active ingredients of low solubility are formulated together with selected excipients in order to ensure adequate absorption of the active ingredient for example in the gastrointestinal tract.")). The '347 patent, however, does not disclose or refer to ritonavir, lopinavir, or any other protease inhibitor.[2]

[2] Mylan disagrees with AbbVie's statements regarding the alleged development of the product at issue in this lawsuit as well as its other ritonavir-containing products. This information is not relevant to claim construction. This information, including that which relates to other products not at issue in this lawsuit, is entirely irrelevant to claim construction. To the extent that AbbVie's statements merit a response, Mylan directs the Court to the development background of AbbVie's ritonavir product Norvir® that Mylan provided to the District of Delaware. (*See* Pls.' Br., Ex. 18 at 13-15, 18.) [redacted]

III. LEGAL STANDARD

The "goal of claim construction is to determine what an ordinary artisan would deem the invention claimed by the patent, taking the claims together with the rest of the specification." *See AstraZeneca AB v. Mut. Pharm. Co., Inc.,* 384 F.3d 1333, 1337 (Fed. Cir. 2004); *see also DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1322 (Fed. Cir. 2001) (noting that claim construction "is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims" (quotation omitted)). In construing patent claims, "the court should look first to the intrinsic evidence of record, *i.e.,* the patent itself, including the claims, the specification and, if in evidence, the prosecution history. Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Vitronics Corp. v. Conceptronic, Inc.,* 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996)).

The claim construction inquiry thus begins with the plain and ordinary meaning of the claims, which define the scope of the right to exclude. *See Vitronics* 90 F.3d at 1582. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.,* 415 F.3d 1303, 1313 (Fed. Cir. 2005). However, a patentee may "choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, ***as long as the***

[redacted]

special definition of the term is clearly stated in the patent specification or file history." *Vitronics,* 90 F.3d at 1582 (emphasis added).

In fact, the specification is "the single best guide to the meaning of a disputed term" and is "[u]sually . . . dispositive." *Phillips*, 415 F.3d at 1315. "[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313 (citation & quotations omitted); *see also Vitronics* 90 F.3d at 1582 ("[C]laims must be read in view of the specification, of which they are a part."). "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998); *see also Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.,* 493 F.3d 1358, 1363 (Fed. Cir. 2007) (same). Additionally, the prosecution history "is often of critical significance in determining the meaning of the claims." *Vitronics,* 90 F.3d at 1582 (citing *Markman,* 52 F.3d at 980). "[T]he prosecution history provides evidence of how the PTO and the inventor understood the patent." *Phillips,* 415 F.3d at 1317.

In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. But a court may rely upon extrinsic evidence, such as expert declarations, dictionaries and the like, "to understand the technology and to construe the claims." *Vitronics*, 90 F.3d at 1584 (citing *Markman*, 52 F.3d at 979) ("[A] court in its discretion may admit and rely on prior art proffered by one of the parties, whether or not cited in the specification or the file history ... [as it] can often help to demonstrate how a disputed term is used by those skilled in the art."). Extrinsic evidence, however, "may not be used to vary or contradict the claim language." *Id.* Indeed, when the intrinsic evidence reveals the proper claim

construction, it is improper to rely on unnecessary extrinsic evidence such as expert declarations or testimony to construe the claims. *See C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) ("When an analysis of intrinsic evidence resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence to contradict the meaning so ascertained.").

When a process step is fundamental to a final product, a product claim can also be limited by its manufacturing method or process. *See, e.g., Andersen Corp. v. Fiber Composites, LLC,* 474 F.3d 1361, 1375 (Fed. Cir. 2007) ("process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention"); *see also Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) (no infringement where patentee's prosecution arguments limited patent claims to compound formed by one-step process); *Chimie v. PPG Ind., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) (patentee distinguished "both its product and process claims from [the prior art] and did so by focusing on the necessity of using [its process] to obtain the claimed product," in that the patentee distinguished the prior art because it did not use a particular step and thus was not capable of "ultimately providing a homogeneous and solid particulate product" as the claims required); *AFG Ind., Inc. v. Cardinal IG Co., Inc.*, 224 Fed Appx. 956, 958 (Fed. Cir. 2007) ("when the product's distinction from the prior art depends on how it was produced, and when the validity of the patent depends on use of a particular process, the claims are construed in the manner that will sustain their validity, when such construction is supported by the record").

IV. ARGUMENT

A. "Formulated as a Solid Dispersion of Amorphous Ritonavir in a Matrix Including a Water Soluble Polymer" (Claim 1 of the '752 patent)

AbbVie's Proposed Construction	Mylan's Proposed Construction
Exists as a solid dispersion of amorphous ritonavir in a matrix including a water soluble polymer	A solid dispersion of amorphous ritonavir formulated by dissolving ritonavir in a solvent and dispersing the ritonavir-solvent mixture in a water soluble polymer, followed by evaporation of the solvent

The Court should construe "formulated as a solid dispersion of amorphous ritonavir in a matrix including a water soluble polymer" to mean "a solid dispersion of amorphous ritonavir formulated by dissolving ritonavir in a solvent and dispersing the ritonavir-solvent mixture in a water soluble polymer, followed by evaporation of the solvent," as set forth in the specification of the '752 patent, supported by the original prosecution history, and reiterated in the Reexamination prosecution history. Both the patent specification and the prosecution history demonstrate that the inventors of the '752 patent viewed the solvent evaporation process as the essential factor allegedly distinguishing the invention from prior art formulations. *See*, *e.g.*, *Andersen Corp.,* 474 F.3d at 1375 ("process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention"). The Court should thus adopt Mylan's construction.

With respect to the specification of the '752 patent, the "Background of the Invention" section recognizes that there are multiple ways of creating a solid dispersion dosage form and that polyethylene glycol ("PEG") "solid dispersion formulations are generally known to improve the dissolution and bioavailability of many compounds." (Ex. C at col. 1, ll. 42-50; col. 2, ll. 22-24). But the specification disparages these prior art, "generally known" formulations because, according to the '752 patent applicants, it was "demonstrated that this was unable to improve the

bioavailability of an HIV protease inhibitor."[3] (*Id.* at col. 2, ll. 25-27). Accordingly, the specification purports to provide an allegedly novel "*preparation* of solid dispersion systems for protease inhibitors with improved dissolution and oral bioavailability." (*Id.* at col. 2, ll. 65-67) (emphasis added). The specification then discloses the method for preparing the allegedly novel solid dispersion system of the invention via solvent evaporation, as follows:

> A solid (molecular) dispersion comprising an HIV protease inhibiting compound may be prepared by dissolving or dispersing the HIV protease inhibiting compound in a sufficient amount of an organic solvent followed by dispersion into a suitable water soluble carrier … The organic solvent (preferably ethanol) may then be evaporated away, leaving the drug dispersed/dissolved in the molten matrix, which is then cooled. The solid matrix has the compound finely dispersed (molecular dispersion) in such a way that dissolution of the drug is maximized, thus improving the bioavailability of a drug exhibiting dissolution rate limited absorption. Ease of manufacturing is also an attribute to this type of formulation. Once the organic solvent is evaporated to yield a solid mass, the mass may be ground, sized, and optionally formulated into an appropriate delivery system.

(*Id.* at col. 3, ll. 1-40). While the specification discloses that the preparation of the solid dispersion can include different ingredients and various protease inhibitors (including ritonavir (ABT-538) and lopinavir (ABT-378)), the method of preparation described in each instance throughout the specification is the same solvent evaporation method described above. (*Id.* at col. 5, ll. 30-62).

Similarly, during prosecution, the patent applicants emphasized the significance of the process used and distinguished the claimed invention from the prior art on this basis because,

[3] Contrary to AbbVie's assertions, the inventors did not "expressly provide[] a number of alternative methods for making solid dispersions." (Pls.' Br. at 12.) Rather, the inventors disclosed that these methods were known in the art but alleged that they were *not* successful in formulating solid dispersions of protease inhibitors. (Ex. C at col. 2, ll. 22-29.) The inventors thus disparaged the "melting (or fusion), solvent, or melting-solvent methods" that were known (*id.* at col. 1, ll. 42-46) and subsequently asserted that their method – the solvent evaporation method specifically disclosed in the "Detailed Description of the Invention" section of the '752 patent – is what achieved a "solid dispersion pharmaceutical formulation of a retroviral protease inhibitor which is more stable and has enhanced bioavailability." (*Id.* at col. 2, ll. 30-32.)

according to the '752 patent inventors, the prior art at issue did not disclose the process they had employed. For example, during prosecution, the Applicants explained to the Examiner that the amorphous nature of the protease inhibitor and the resulting improved bioavailability separated this invention from prior art formulations because these claimed features and improvements are a direct result of the alleged invention's use of the solvent evaporation method:

> ***Aungst et al does not teach the evaporation procedure*** under which the solvents are evaporated, therefore the assumption that DMP323 is in amorphous form does not have a foundation … the solvent used is a mixture of ethanol and methylene chloride without any description ***as to how the process of evaporation*** is conducted, therefore the assumption that DMP323 is in amorphous form does not have a foundation … The fact that the formulations of Al-Razzak *et al* do not comprise HIV protease inhibitor in amorphous form ***can be deduced from the process of making the formulations***.

(Ex. I at 11-12). It is thus clear from the original prosecution history that the Applicants intended the process disclosed in the specification to be central to the invention, as the solvent evaporation method is how the inventors reportedly achieved the amorphous nature of the drug and improved bioavailability, consistent with the specification's differentiation of the alleged invention from the prior art formulations that were allegedly "unable to improve the bioavailability of an HIV protease inhibitor." (Ex. C at col. 2, ll. 24-26.)

The history of the '752 patent's reexamination further supports Mylan's construction. During reexamination proceedings, AbbVie attempted to overcome prior art that, according to AbbVie, failed to disclose the ***process*** employed by the inventors to obtain the claimed ritonavir product:

> [T]he ***production method disclosed in the '752 Patent is elegant and is different*** from the methods disclosed in the Martin Poster and the Dias Poster. For example, in the '752 Patent, a small amount of solvent is used to dissolve only the API, which is subsequently dispersed in a molten polymer matrix that itself contains no solvent. Further, the dispersion and solidification process disclosed in the '752 Patent, is ***a controlled process*** that allows any residual solvent to evaporate from the solid dispersion. In contrast, as explained in detail *infra*, ***a***

> ***controlled drying process and limited solvent usage are not disclosed within either the Martin Poster or the Dias Poster***, as noted by Dr. Bates. Without limited solvent usage and controlled drying conditions, the solvent content of the final materials in those posters will necessarily produce a material different from the solid dispersion that is claimed within the '752 Patent.

(Ex. J at 18-19 (emphasis added and internal citations omitted)).

AbbVie even attempted to broaden the scope of the '752 patent during the reexamination proceedings to encompass other processes or methods, specifically the melt-extrusion process, for making solid dispersions, despite the fact that the inventors' invention only disclosed and encompassed (and likely enabled) the solvent-evaporation method. Specifically, in attempting to overcome the prior art in the Examiner's November 26, 2013 Action Closing Prosecution, the Patent Owner sought to rely on the alleged success of AbbVie's Kaletra product made by melt-extrusion. (Ex. K at 16-17). The Examiner in the reexamination proceedings, however, rejected the Patent Owner's assertions because the melt extrusion process was not disclosed or described in the '752 patent. (*See* Ex. L at 31-32; Ex. M at 30). Out of an apparent abundance of caution, however, the Examiner further rejected the claims anyway based on prior art that specifically disclosed melt-extrusion processes, "***in the event*** that Patent Owner argues that [the '752 patent encompasses] the melt extrusion method, although such a method is not specifically described in the specification or in the original claims." (Ex. M at 23-24). In short, though neither the Patent Owner nor the inventors had referenced or disclosed making the alleged invention using the melt extrusion method, the Examiner rejected the claims as obvious anyway since melt extrusion methods were already known in the art and thus did not provide any novelty to the '752 patent.[4]

[4] AbbVie also cites to the Examiner's statement that "the claims, directed to a pharmaceutical composition comprising amorphous ritonavir formulated as a solid dispersion in a matrix including a water soluble polymer, *are not limited* to the pharmaceutical composition of Example 1," to insinuate that the Examiner agreed that the claims cover the melt extrusion process. (*See* Pls.' Br. at 13-14.) This is not accurate. The Examiner's statement is merely directed to noting

Even now, in its Opening Brief, [redacted] Yet, AbbVie seeks to ignore the ***is formulated as*** limitation of the disputed term and the essential process steps disclosed to achieve the claimed formulations. AbbVie also attempts to write out the "is formulated as …" language of Claim 1 by referencing the alleged process steps in the dependent claims. (*See id.* at 11). Specifically, AbbVie asserts that the inventors "knew how to [claim process steps]" since Claims 29-38 claim a solid dispersion that "*is prepared* through cooling a molten matrix." (*See id.* at 11-12). However, AbbVie fails to explain why it construes "is prepared" as reciting a process step, but refuses to construe "is formulated" as a process step as well. Dependent Claims 29-38 merely add an *additional* process step (cooling the molten matrix) to the other process steps encompassed by the disputed limitation of the independent claim requiring the formulation to be "formulated as a solid dispersion of amorphous ritonavir in a matrix including a water soluble polymer." It is thus clear that the inventors indeed knew how to claim process steps, and did so by using both the "is formulated" and "is prepared" language.

AbbVie, however, seeks to redraft Claim 1 to eliminate what the inventors intended to be an essential element of the claim, to read instead as follows: "A pharmaceutical composition comprising ritonavir, wherein ritonavir in said composition *is a solid dispersion of amorphous ritonavir in a matrix including a water soluble polymer.*" But this is not what the inventors claimed. AbbVie's attempt to improperly re-draft the claim for purposes of litigation should be rejected; construing the claim term at issue to encompass the specific process employed and described in the patent is appropriate and necessary to respect the inventors' intent as well as the

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that the claims are not limited to *the pharmaceutical composition* of Example 1, *i.e.*, the specific formulation components and component amounts used in the example. The Examiner's statement had no bearing on whether the claims encompassed any other processes other than the essential solvent evaporation method disclosed.

true scope of the claimed invention. *See, e.g., Andersen Corp.* , 474 F.3d at 1375 ("process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention"); *see also Chimie*, 402 F.3d at 1384 (patentee distinguished "both its product and process claims from [the prior art] and did so by focusing on the necessity of using [its process] to obtain the claimed product," in that the patentee distinguished the prior art because it did not use a particular step and thus was not capable of "ultimately providing a homogeneous and solid particulate product" as the claims required); *AFG Ind., Inc. v. Cardinal IG Co., Inc.*, 224 Fed Appx. 956, 958 (Fed. Cir. 2007) ("when the product's distinction from the prior art depends on how it was produced, and when the validity of the patent depends on use of a particular process, the claims are construed in the manner that will sustain their validity, when such construction is supported by the record").

The Court should thus adopt Mylan's proposed construction and construe the "formulated as …" limitation to mean "a solid dispersion of amorphous ritonavir formulated by dissolving ritonavir in a solvent and dispersing the ritonavir-solvent mixture in a water soluble polymer, followed by evaporation of the solvent."[5]

[5] The District of Delaware did not adopt AbbVie's or Mylan's construction for the "formulated as …" claim term. Rather, the District of Delaware held that "no construction is necessary" based in part on a statement from the reexamination prosecution history in which the Examiner states that "[t]he pharmaceutical composition as recited in the claim encompasses its preparation by any process…." (*See* Pls.' Br., Ex. 17 at 5-6.) However, this statement goes on to make clear that the Examiner was responding to the Patent Owner's argument that the process claimed in the patent was "a controlled process" with "require[d] stability, in vivo/in vitro correlation, good bioavailability or no residual solvents." (*See* Pls.' Br., Ex. 16 at 8, 10, 21, 33 ("The pharmaceutical composition as recited in the claim encompasses its preparation by any process, *and allows for any degrees of stability, bioavailability, in vivo/in vitro correlation, as well as any amounts of residual solvents*")). Mylan respectfully disagrees with the District of Delaware's view of the record and respectfully submits that the record does not support the conclusion that the Examiner intended this statement to broaden the claims to include methods other than the solvent evaporation method disclosed in the specification.

B. "Solid Solution" (Claims 4 and 5 of the '349 Patent, Claims 19 and 29 of the '015 Patent, Claim 2 of the '878 patent, and Claims 1, 5, 11-14, 19, 23-26, 28 of the '952 Patent)

AbbVie's Proposed Construction	Mylan's Proposed Construction
A system in a solid state wherein the drug is molecularly dispersed throughout a matrix such that the system is chemically and physically uniform or homogeneous throughout, which may include but is not limited to individual drug molecules completely surrounded by the matrix	A system in a solid state wherein the drug is molecularly dispersed throughout a matrix such that the system is chemically and physically uniform or homogeneous throughout

Mylan's construction for the term "solid solution" adopts verbatim the definition set forth in the '349, '015, '878 and '952 patents and adopted by the District of Delaware's Markman Order:

> The term "solid solution" defines a system in a solid state wherein the drug is molecularly dispersed throughout a matrix such that the system is chemically and physically uniform or homogenous throughout.

(*See* Ex. D at col. 1, ll. 44-47; Ex. N at col. 1, ll. 42-45; Ex. O at col. 1, ll. 44-47). AbbVie's construction, however, seeks to improperly alter this explicit definition by adding a "proviso" that aims to write out and ignore the requirement that the "drug is *molecularly dispersed* throughout a matrix." The District of Delaware specifically rejected AbbVie's prior attempt to alter the definition in such a manner, and so too should this Court. *See Martek Biosciences Corp.,* 579 F.3d at 1380; *see also Vitronics,* 90 F.3d at 1582.

In the Delaware Action, AbbVie originally sought to construe "solid solution" as "a solid dispersion that is chemically and physically uniform or homogeneous throughout or consists of one phase (as defined in thermodynamics)," altogether avoiding the "molecularly dispersed" language of the explicit definition. (*See* Pls.' Br., Ex. 18 at 45.) AbbVie argued that "molecularly dispersed" simply means "intimately mixed," and focused its argument on the

notion that a "solid solution" does not mean that every individual drug molecule in a solid solution is surrounded by the matrix.[6] (*Id.* at 46.) The District of Delaware properly rejected AbbVie's arguments and adopted Mylan's proposed construction. (*See* Pls.' Br., Ex. 17 at 7.)

AbbVie now proposes a construction that adopts the explicit definition of "solid solution," but then adds the following language: "may include but is not limited to individual drug molecules completely surrounded by the matrix." There is no legal basis (and AbbVie fails to set forth any such basis) for altering the inventors' explicit definition in such a manner. In fact, this "proviso" language AbbVie seeks to add mirrors the very argument AbbVie championed and the District of Delaware rejected that sought to write out or ignore the "molecularly dispersed" requirement of the explicit definition. It is thus clear that AbbVie proposes this additional language only to again render obsolete the requirement that components of a "solid solution" be "molecularly dispersed" just as AbbVie attempted to do in the Delaware Action.

Indeed, much of AbbVie's argument in support of its proposed construction focuses on "particle size" or the "mixing of components" in an attempt to draw attention and meaning away from the "molecularly dispersed" language. However, "molecularly dispersed" clearly refers to the dispersion of *molecules,* not particles or components, which may consist of multiple molecules. AbbVie's argument that "[p]ersons of ordinary skill in the art, as well as the inventors, therefore viewed solid solutions in terms of degree of mixing, particle size, and phase" is simply misplaced. (Pls.' Br. at 16.) Indeed, the specification only references "particle size" with respect to the broad description of "solid dispersions," not with respect to the more narrow,

[6] In the Delaware Action, AbbVie first argued that the term "molecularly dispersed" was ambiguous, despite contradictorily admitting that "the term 'molecular dispersion' is known to the skilled worker." (*See* Pls.' Br., Ex. 18 at 56). AbbVie ultimately abandoned that argument in favor of replacing "molecularly dispersed" with "intimately mixed."

molecularly dispersed "solid solutions." (*See* Ex. D at col. 2, ll. 10-14.) For example, the '349 patent makes clear that a "'solid dispersion' encompasses systems having small particles" (*id.* at col. 2, ll. 10-11), but that a solid solution, which is a specific type of solid dispersion[7], is one in which "the drug is molecularly dispersed throughout a matrix such that the system is chemically and physically uniform or homogenous throughout." (*Id.* at col. 1, ll. 44-46.)

AbbVie's analogy to liquid solutions is misplaced. One of ordinary skill in the art would know that a homogenous, liquid solution does not contain particles; rather, the drug component is completely dissolved *at the molecular level* and dispersed throughout the system, much like the dissolution of sugar in water that results in a clear, homogenous liquid solution. As explicitly defined by the inventors of the relevant asserted patents, a "solid solution" also comprises a system in which the drug component is "molecularly dispersed" (i.e., dispersed at a *molecular* level), but is in a solid state rather than a liquid state. The inventors similarly defined "glassy solution" as "a homogeneous, glassy system in which a solute is *dissolved* in a glassy solvent." (*Id.* at col. 2, ll. 18-20.) AbbVie's effort to broaden "solid solution" to encompass systems with dispersed drug "particles" rather than dispersed or dissolved drug molecules thus falls flat.

AbbVie also supports its alteration of the explicit definition by erroneously arguing that "Mylan has previously urged during claim construction proceedings … that the phrase 'molecularly dispersed' means *only* that *every* active ingredient molecule is surrounded by molecules of the matrix materials." But it is the inventors of the '015, '349, '878, and the '952 patents, not Mylan, who described "molecular dispersions" as formulations in which a drug is embedded in a matrix such that "[t]he matrix behaves like a true solvent, ***i.e. every active ingredient molecule is surrounded by molecules of the matrix materials***." (Ex. P at

[7] The '349 patent discloses that both "solid solutions" and "glassy solutions" are specific types or subsets of "solid dispersions." (Ex. D at col. 2, ll. 14-18.)

MYLB00009194, lines 31-34 (emphasis added)). The inventors' own description of what they mean by "molecular dispersion" should not be ignored. Mylan's argument has been and remains that "solid solution" should be construed according to the explicit definition provided by the inventors, specifically: "a system in a solid state wherein the drug is molecularly dispersed throughout a matrix such that the system is chemically and physically uniform or homogeneous throughout." This definition is the explicit, lexicographic definition provided by the specifications of the relevant patents, is consistent with the knowledge of one of ordinary skill in the art, and is supported by the inventors' own understanding of the term "molecular dispersion" as demonstrated by the asserted patents and the inventors' related patent documentation.

Accordingly, the Court should adopt the patent applicants' explicit definition of "solid solution" as proposed by Mylan.

C. "Solid or Glassy Solution" and "Glassy or Solid Solution" (Claims 5, 9 of the '613 Patent and Claims 4, 8 of the '899 Patent)

AbbVie's Proposed Construction	Mylan's Proposed Construction
A solid dispersion that is chemically and physically uniform or homogenous throughout or consists of one phase (as defined in thermodynamics), wherein: • a solid solution is a system in a solid state wherein the drug is molecularly dispersed throughout a matrix such that the system is chemically and physically uniform or homogenous throughout, which may include but is not limited to individual drug molecules completely surrounded by the matrix, and • a glassy solution is a homogeneous, glassy system in which a solute is dissolved in a glassy solvent.	A solid dispersion that is chemically and physically uniform or homogenous throughout or consists of one phase (as defined in thermodynamics).

Once again, Mylan's proposed construction of the "solid or glassy solution" and "glassy or solid solution" terms adopts verbatim the definition set forth in the '349, '015, '878 and '952 patents. The specification of these patents specifically states:

> When said dispersion of the components is such that the system is chemically and physically uniform or homogenous throughout or consists of one phase (as defined in thermodynamics), such a solid dispersion will be called a "solid solution" or a "glassy solution."

(*See* Ex. D at col. 2, ll. 13-17.) Even AbbVie agrees that this portion of the specification defines these disputed terms. AbbVie, however, again seeks to alter an explicit definition of the inventors, this time by adding language that purports to separately define "solid solution" and "glassy solution." The parties never identified these two terms as requiring construction, however, and that is because they are not terms used in the patent claims. The relevant terms are "solid or glassy solution" and "glassy or solid solution," which the inventors refer to in the claims and define in the patent specification as a collective term. (*Compare, e.g.,* Ex. Q at Claim 9 ("wherein said solid dispersion is a *glassy or solid solution*") and Claim 18 ("wherein said solid dispersion is a *solid solution* or a *glassy solution*").)

AbbVie offers no legal or factual support for its attempt to shoehorn constructions of "solid solution" and "glassy solution" into the construction of "solid or glassy solution" and "glassy or solid solution." Moreover, AbbVie is again pushing for the same construction of "solid solution" that the District of Delaware rejected as unsupported by the intrinsic record in connection with the '349, '015, '878 patents. (Pls.' Br., Ex. 17 at 7).

Therefore, the Court should adopt the parties' common understanding of the meaning of "solid or glassy solution" (and vice versa) and reject AbbVie's attempt to manufacture a claim construction issue that simply does not exist.

D. "Without Food" ('952 Patent)

AbbVie's Proposed Construction	Mylan's Proposed Construction
Means that the patient has not eaten just before, during, and just after taking the medication	Indefinite

The disputed term "without food" is neither defined nor described in the intrinsic record of the '952 patent. While the term itself may seem straightforward, its inclusion in many of the patent claims alongside the phrase "or under a fasting condition," which also means without food, creates ambiguity that is unresolved by the intrinsic record. (*See* Ex. E at Claims 1 and 11-13). The parties' agreed-upon construction of "under a fasting condition" underscores the ambiguity. In negotiating claim constructions, the parties agreed that "under a fasting condition" means 10 hours of abstinence from eating prior to dosing and 4 hours post-dosing, *although those skilled in the art will recognize various other timings that would also qualify as a fasting or fed state*." (*See* D.I. 144 at 2 (emphasis added)). Thus, the parties' construction recognizes that "under a fasting condition" would be understood by persons of ordinary skill in the art to describe taking medication without having consumed food for virtually any period of time before or after taking the medication. As the '952 patent specification explains, "a *fasted state* refers to the fact that a patient has not eaten for a given amount of time before taking a dose of medication, as well as not eating for a given amount of time after taking the dosage form." (The '952 patent at col. 9, ll. 40-44.) That leaves "without food," which is not defined in the patent, meaningless, and, thus, the claims in which it appears indefinite. *See*, *e.g.*, *Cephalon Inc. v. Abraxis Bioscience, LLC*, Appeal No. 2014-1411 (consol.), 2015 U.S. App. LEXIS 10152, at *9 (Fed. Cir. June 17, 2015) ("construing the two terms to have no difference in meaning would render one of the terms superfluous, which is disfavored in claim construction").

Patent claims and claim terms are indefinite if they "fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). It is not enough that the Court may be able to "ascribe *some* meaning to a patent's claims." *Id.* at 2130. And, a defined claim "is still indefinite if a person of ordinary skill in the art cannot translate the definition into a meaningfully precise claim scope." *Halliburton Energy Servs. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008).

AbbVie's proposed construction actually exacerbates the indefiniteness problem by adding the term "just," as though "just," when referring to a period of time, has a commonly understood meaning among persons of ordinary skill in the art. Yet, AbbVie offers no support for this assumption. Regardless, AbbVie's proposed construction falls squarely within the parties' agreed-upon construction and the '952 patent's description of "under a fasted condition." Therefore, "without food" is indefinite, as are the claims in which the term appears.

E. "Molecular Dispersion" (Claims 1-3, 5, 6, 8-10, 20, 21, and 23 of the '347 Patent)

AbbVie's Proposed Construction	Mylan's Proposed Construction
a system in which a substance is homogeneously dispersed in a solvent	a system in which a substance is homogeneously dispersed in a solvent at a molecular level

The specification of the '347 patent states that "[t]he term 'molecular dispersion' is known to the skilled worker." (Ex. F at col. 7, ll. 56-57). It further states that "'molecular dispersion' … *essentially describes* systems in which a substance … is homogeneously dispersed in a solvent." (*Id.* at col. 7, ll. 57-60). Unlike the explicit definition set forth for the "solid solution" term, this general description of "molecular dispersion" is just that – it is not an explicit definition or an instance in which the inventors were acting as lexicographers. An applicant may

be his or her own lexicographer by clearly setting forth a definition of a term that is *different* from its ordinary and customary meaning as would be understood by those skilled in the art. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). However, neither Plaintiffs nor the *Markman* opinion in the Delaware Action identify any evidence that the inventors of the '347 patent intended to define "molecular dispersion" differently from its ordinary and customary meaning. Rather, it is clear the patentees intended "molecular dispersion" to be understood in accordance with its plain meaning. *See Vitronics*, 90 F.3d at 1582 (claim construction begins with the claim term's plain meaning). Mylan's proposed construction adopts the '347 patent's plain meaning description of "molecular dispersion" and modifies it appropriately by adding the phrase "at a molecular level" to add clarity consistent with the plain language of the term itself: "*molecular* dispersion."

AbbVie, on the other hand, seeks to write out the "molecular" portion of the term, just as it sought to exclude "molecularly dispersed" from the explicit definition of "solid solution" as explained above. Again, it is evident that AbbVie seeks to impermissibly broaden the claims to include any dispersion without regard to the modifier "molecular" that is used in the term itself. But the specification of the '347 patent makes clear that the dispersion at issue occurs at the molecular level. For example, the specification describes "molecular dispersions" as corresponding to a state of maximum possible homogenization of a drug component in a matrix such that the system is essentially free of drug crystals or particles. (*See* Ex. F at col. 8, ll. 1-22). The specification further states that "the solvent usually forms a matrix." (*Id.* at col. 7, ll. 60-61). One of ordinary skill in the art would understand such maximum homogenization and formation of a matrix equates to a molecular dispersion – *i.e.*, a dispersion at the molecular level in which the *molecules* are dispersed throughout the matrix. (*See, e.g.* Ex. D. at col. 1, ll. 44-46 (A "'solid

solution' defines a system in a solid state wherein the drug is *molecularly dispersed throughout a matrix* ….''); *see also* Ex. C at col. 3, ll. 32-36 ("The solid matrix has the compound finely dispersed (molecular dispersion) in such a way that dissolution of the drug is maximized")).

Even AbbVie's own proffered evidence from the intrinsic record supports Mylan's construction. AbbVie cites to U.S. Patent No. 6,632,455 ("the '455 patent"), which is entitled "Molecular Dispersion Composition with Enhanced Bioavailability." (Pls.' Br. at 24.) The '455 patent discloses that the term "molecular dispersion," as used therein, "refers to a condition in which: (a) compound (I) is in a substantially amorphous form and is dispersed in a polymer matrix (***also known as a "solid solution***")." (Pls.' Br., Ex. 24 at col. 2, ll. 60-63 (emphasis added)). This is consistent with the '347 patent, which discloses that when "molecular dispersion systems are solid … they are referred to as solid solutions." (Ex. F at col. 8, ll. 1-2.) AbbVie even admits as much. (*See* Pls.' Br. at 5 ("When the components are even more intimately mixed, the solid dispersion is called a solid solution or a molecular dispersion.").) Thus, like the proper construction for the term "solid solution" above, which similarly requires dispersion at the molecular level ("molecularly dispersed"), so too should the "molecular dispersion" construction.

Additionally, the '455 patent specifically refers to the "amorphous form" of the component dispersed, further demonstrating that the dispersion is *at the molecular level,* since the component no longer contains crystalline particles; the molecules of the crystalline lattice have been modified and are no longer "arranged in a long-range, ordered, repeating structure," but instead are homogeneously dispersed throughout the matrix. (*See, e.g.,* Pls.' Br. at 2 ("[i]nstead of having the molecules arranged in a crystal lattice, amorphous solids are composed of molecules arranged in a more random configuration"); *id.* at 20.) Again, this is consistent

with the '347 patent, which discloses that when a system is free of crystalline particles "(essentially ***amorphous*** or crystal-free formulations)," it corresponds to a state of "maximum possible homogenization," as "[t]here are no interfaces in a formulation which is a molecular dispersion." (Ex. F at col. 8, ll. 3-7, 16-23 (emphasis added)).

As Mylan's construction is consistent with the plain meaning of the claim term and wholly supported by the intrinsic evidence, the Court should construe "molecular dispersion" to mean: "a system in which a substance is homogeneously dispersed in a solvent at a molecular level."

F. "Self-Emulsifying" (Claims 1-3, 5, 6, 8-10, 20, 21, and 23 of the '347 Patent)

AbbVie's Proposed Construction	Mylan's Proposed Construction
Dissolves upon contact with aqueous media to form an emulsion, with negligible input of mechanical energy, and without requiring the addition of further components in the aqueous media to form the emulsion	Capable of spontaneously forming an emulsion upon contact with aqueous media

From the Abstract (beginning of the specification) to the claim term itself (the end of the specification), the '347 patent is consistently clear that "self-emulsifying" means "capable of spontaneously forming an emulsion upon contact with aqueous media." First, the Abstract states that "formulations [of the invention] *spontaneously* form emulsions in water or aqueous media." (*Id.* at Abstract). The specification then further supports and expands upon this statement, specifically disclosing that "formulations of the invention represent self-emulsifying systems. Emulsions are formed when the formulations *come into contact* with aqueous media … [and u]nder the conditions of use, the emulsions normally form *spontaneously*." (*Id.* at col. 22, ll. 41-60). Next, the term itself, "*self*-emulsifying," clearly connotes that the "emulsifying" is achieved on its own, since it is modified by the term "self," rather than achieved with the input of

mechanical energy. (*See id.* at col. 22, ll. 60-62 ("In particular, negligible input of mechanical energy, e.g. stirring and/or shear energy, is necessary.").)

Finally, the inventors themselves employed the construction Mylan now advocates in dependent claims 20 and 25, where they describe the "self-emulsifying formulation" of claim 1 as one "capable of spontaneously forming an emulsion upon contact with aqueous media." (*See id.* claims 20 and 25). The term "self-emulsifying" provides an antecedent basis for this language in claims 20 and 25; therefore, this language effectively defines "self-emulsifying." *See Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) ("[D]ependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention."); *see also Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995) ("[W]hen the claim drafter chooses to use *both* the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects.") *cited and quoted parenthetically in Catalina Mktg Int'l*, 289 F.3d at 808.

The construction AbbVie now proffers, which is the compromise construction the District of Delaware ultimately crafted itself, is itself ambiguous. First, it is not clear what level of mechanical energy is considered to be "negligible." Indeed, none of the examples or other descriptions in the '347 patent describe the input of *any* mechanical energy to the alleged inventions. (*See, e.g.,* Ex. F at Examples 1-13 (noting simply that formulations were allowed to dissolve in water without any input of energy).) AbbVie thus focuses on a single prior art reference (Bachynsky et al.) cited in the background section of the '347 patent that describes "self-emulsifying" systems as "a mixture of oil and surfactant which, when mixed with an

aqueous system *under mild agitation*, forms a fine emulsion." (*See* Pls.' Br. at 27 (emphasis added)). However, the '347 patent's reference to this (and other) prior art in the background section purports to distinguish the alleged inventions of the '347 patent from the prior art. (*See, e.g.,* Ex. F at col. 1, ll. 51-53 (referencing the "known disadvantages" of these prior art "self-emulsifying" systems).) The '347 patent asserts that the alleged inventions set forth therein contain different formulation components (*see, e.g., id.* at col. 1, l. 66-col. 2, l. 11) and self-emulsify *spontaneously* (*see, e.g., id.* at col. 22, ll. 59-60). As a result, Bachynsky's description of "self-emulsifying" does not control the meaning or construction of "self-emulsifying" as set forth by the remaining sections of the '347 patent specification. It is clear the inventors of the '347 patent intended their invention to be different than prior art formulations because the alleged "self-emulsifying" invention is "capable of spontaneously forming an emulsion upon contact with aqueous media."

Second, AbbVie's argument that the spontaneous formation of the emulsion is merely a preferred embodiment is erroneous and was specifically rejected by the District of Delaware. (*See* Pls.' Br., Ex. 17 at 8-9). AbbVie contends that the specification's statement that "[u]nder the conditions of use, the emulsions *normally* form spontaneously" indicates a preferred embodiment. It does not. Rather, this statement refers to the "conditions of use" of the formulation – as they are disclosed in the specification. This is evident upon reading the entirety of the relevant passage in the specification:

> Under the conditions of use, the emulsions normally form spontaneously. In particular, negligible input of mechanical energy, e.g. stirring and/or shear energy, is necessary. Thus, formulations of the invention can initially be produced in the absence of solvents. *The formation of the emulsion then takes place, depending on the use, when contact is made with an aqueous medium, in the drug form sector before administration by preparing an appropriate dosage form or after administration on contact with a suitable body fluid*.

(Ex. F at col. 22, ll. 59-67 (emphasis added)). The passage explains different conditions of use that may vary the spontaneity of the emulsion formation: either (a) "before administration by preparing an appropriate dosage form" (for example, adding the solid formulation to water to form a liquid dosage form, in which contact with water is immediate) or (b) "after administration on contact with a suitable body fluid" (for example, a solid dosage form that must first travel through portions of the body before contacting water). There is simply no statement or description in the specification indicating that a spontaneously forming emulsion, so evident by the "*self*-emulsifying" term itself, is nothing more than a preferred embodiment. Rather, and as explained above, the spontaneity of the emulsion is a requirement of the invention as a whole, as set forth by the Abstract, the written description, and the plain meaning of the term itself, as confirmed by the District of Delaware.

Third, AbbVie's argument based on claim differentiation is similarly mistaken. Claims 20 and 25 do not add an additional limitation regarding the spontaneity of the emulsion. Rather, these claims add the limitation – thus further narrowing the claims – that the formulation is capable of forming the required, spontaneous emulsion upon contact with a particular aqueous media: one that *contains at least 50% by weight water*. (*Id.* at Claims 20, 25). Indeed, no other claim adds this specific limitation, which is focused on the *content* of the aqueous media, not the *spontaneity* of the emulsion formation. The District of Delaware recognized this distinction as well and rejected Plaintiffs' claim differentiation argument outright, and agreed with Mylan that the "spontaneous" requirement in Claim 25 was not an additional limitation.

Lastly, the language in AbbVie's proposed construction, "without requiring the addition of further components in the aqueous media to form the emulsion," is ambiguous and unsupported by the specification of the '347 patent. AbbVie cites the '347 patent at column 1,

lines 15-65, but nothing in this portion of the background section of the specification supports the inclusion of AbbVie's proffered language. This section merely purports to describe prior art liquid emulsions as compared to prior art solids that *form* liquid emulsions once added to aqueous systems. There is simply no discussion of the requirement of any "further components in the aqueous media" for either the liquid emulsions or the emulsion forming solids described.[8]

Accordingly, the Court should adopt Mylan's construction and construe "self-emulsifying" to mean "capable of spontaneously forming an emulsion upon contact with aqueous media."

V. CONCLUSION

For the foregoing reasons, Mylan respectfully requests that this Court adopt Mylan's proposed constructions for each of the disputed claim terms.

Respectfully submitted this 30th day of July, 2015.

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[8] Respectfully, the District of Delaware did not explain the basis for the "without requiring the addition of further components in the aqueous media to form the emulsion" language in its construction.

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CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of July , 2015, I electronically filed the foregoing Responsive Claim Construction Brief with the clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to the following counsel of record:

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